

REMARKS / ARGUMENTS

Claims 1-3, 6 and 8-12 remain pending in this application. No claims have been canceled or added.

Priority

Applicants request acknowledgment of the claim for priority and receipt of the priority document at the International Phase

Information Disclosure Statement

On September 2, 2001 Applicants filed an Information Disclosure Statement. On the initialed PTO-1449 Form returned with the Office Action, the Examiner crossed off a reference to JP11-211731 and wrote "No Characterization". Applicants are resubmit this document along with the English abstract and a PTO-1449 Form. This document is discussed in the present specification.

The Examiner has apparently newly cited JP 4-128657, but did not include a PTO Form 892. Therefore, this document is cited on the enclosed PTO-1449 Form so that it may properly be made of record.

35 U.S.C. §112

With respect to the Examiner's rejections under this section, Applicants contend that one of ordinary skill in the art would easily understand the meaning of the terms used in the claims. However, in order to further prosecution and to assist the Examiner, Applicants provide the following comments.

An "analysis parameter" includes information such as the amount of a dispensed sample, reagents used for analysis, the amount used for analysis, a wavelength of absorbance under measurement, a type of reaction process, and a method of calculating a concentration, a standard sample, and a known concentration for use in calibration, etc. Analysis parameters are disclosed from page 1, line 19 to page 2, line 2, for example.

An accuracy management sample is one which has a known concentration. The status of an apparatus can be understood by measuring the accuracy management sample repeatedly in a predetermined interval. If the apparatus is normal, the same test results are obtained. If the apparatus is not normal, the test results are different. Thus, "accuracy management" is the measuring of the accuracy management sample repeatedly and checking the status of the apparatus.

Generally speaking, accuracy management is used to manage a single apparatus. According to the present invention, accuracy management is used to manage different analysis apparatuses in different facilities. As such, it is possible that different test results may be obtained when plural apparatuses which are the

same model of the same manufacturer and use the same reagent are used for the same patient. In an extreme situation, a patient could be judged to be normal in one hospital but judged to be abnormal in another hospital. To avoid this problem, the same accuracy management samples are analyzed using the same reagent in different facilities and a distribution of the test results is evaluated. A "standard value" is a value that is standard in the case that the same accuracy samples are measured. A "deviation calculation" is done for calculating a deviation of a measured value in a different facility for the same accuracy management sample from the standard value. Based on this deviation, a rating of the test result of the apparatus in the facility is evaluated. According to the present invention, this evaluation can be done in a service center using communication lines.

Once again, Applicants contend that the terms used in the claims are terms that would be easily understood by one of ordinary skill in the art. Furthermore, when the claims are read in light of the specification, their meaning can easily be ascertained.

35 U.S.C. §102

Claims 1-3, 6 and 8-12 stand rejected under 35 U.S.C. §102(b) as being anticipated by JP 5-288756 or JP 4-128657. Claims 1-3 and 6-12 stand rejected under 35 U.S.C. §102(e) as being anticipated by Fritchie et al (U.S. Patent No. 6,022,746). These rejections are traversed as follows.

The rejection under this section is based upon an interpretation of the claims that does not include all of the claim limitations. As stated by the Examiner on page 4, lines 9-11, the invention is being construed as a method of monitoring reagents and their controls. However, in light of the explanation provided above with respect to the rejection under 35 U.S.C. §112, it is submitted that the claims contain specific limitations that are neither disclosed nor suggested by any of the cited references. As previously argued, and as acknowledged by the Examiner, Fritchie et al do not disclose or suggest calculating a deviation between the results of analysis and the standard value when an accuracy management sample is newly analyzed by an automatic analyzing apparatus. The results of this analysis are used to verify that the analysis parameters used in the analysis are correct.

JP 5-288756 is cited in the present specification for the use of bar codes. JP 4-128657 discloses that a computer stores analytical results and parameters sent by analytical devices as a set. Neither of these references disclose or suggest the above-mentioned features of the present invention.

Based upon the explanation provided above with respect to the rejection under 35 U.S.C. §112, it should be clear that the pending claims patentably define the present invention over the cited art. The Examiner is hereby invited to contact the undersigned by telephone with any questions.

Appl. No. 09/936,918
Amendment dated May 16, 2006
Reply to Office Action of November 16, 2005

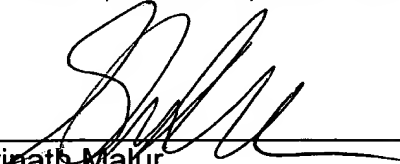
KAS-157

Conclusion

In view of the foregoing, Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

MATTINGLY, STANGER, MALUR & BRUNDIDGE, P.C.

By 
Shrinath Malur
Reg. No. 34,663
(703) 684-1120